K092197 Pg 1 of 2

510(k) Summary

In accordance with the Safe Medical Devices Act of 1990 and in compliance with 21CFR 807, the following serves as the 510(k) Summary information upon which the substantial equivalence determination is based.

Contact Information

Submitter:	BioTex, Inc. 8058 El Rio St. . Houston, TX 77054
Phone:	713.741.0111
Contact Person:	Ashok Gowda
Date Prepared:	6/18/2009

OCT - 6 2009

Device Names

Trade/Proprietary Name:	PhoTex$_{30}$ Diode Laser Series: 980, 810, 940
Common Name:	Diode Laser Series
Classification Name:	Powered surgical laser instrument
Product Code:	GEX
Reg.Class:	II
Reg. Number:	878.4810

Predicate Device

PhoTex$_{15}$ Diode Laser Series: 980, 810, 940 (K060304)
SLT Thermalite Diode Laser Series: 980, 810, 940 (K952661)

Description of Device

The PhoTex$_{30}$ Diode Laser Series are diode lasers emitting radiation in either a continuous-wave (CW), pulsed or external modulation modes in the infrared range at one of the following wavelengths: 980nm, 810nm, and 940nm. The PhoTex$_{30}$ Diode Laser Series provides a means for cutting, coagulation, and vaporization of tissue using a compatible fiber optic delivery accessory. The laser is compatible with any fiber optic delivery accessory terminated with a standard SMA905 connector whose core fiber diameter is 400 micron or larger with a numerical aperture of at least .37.

Indications for Use

The PhoTex30 Diode Laser Series is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in areas of surgery including: gastroenterology, general surgery, plastic surgery, genitourinary (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT) head and neck, orthopedics, ophthalmology, pulmonology, and thoracic surgery.

Comparison to Predicate Device

The PhoTex$_{30}$ Diode Laser Series has been shown to be substantially equivalent to the predicate devices, the PhoTex$_{15}$ Diode Laser Series and SLT Thermalite Diode Laser Series. Based on the technological features, device performance, and indications for use, BioTex, Inc. believes that no significant differences exist between the PhoTex$_{30}$ Diode Laser Series and the predicate devices. Differences were determined to be minor and are each within the specifications listed by the predicate devices and does not raise any concerns regarding the overall safety and effectiveness of the device.

Non-clinical Performance Tests:

Engineering studies have demonstrated the substantial equivalence of the PhoTex$_{30}$ Diode Laser Series to the PhoTex$_{15}$ Diode Laser Series (K060304) and the SLT Thermalite Diode Laser Series (K952661). The studies concluded that the lasers are in compliance with FDA standards 21CFR1040.10 and 21CFR1040.11. In all instances, the lasers functioned as intended and performed in a manner similar to the predicate device when used in accordance with the labeled directions for use and specified indications.

Conclusion

BioTex has demonstrated the PhoTex$_{30}$ Diode Laser Series is substantially equivalent to the predicate devices based on design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

BioTex, Inc.
% Ashok Gowda, Ph.D.
President
8058 El Rio Street
Houston, Texas 77054

OCT - 6 2009

Re: K092197
Trade/Device Name: PhoTex30 Diode Laser Series, Model 980nm, 810nm, 940nm
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 16, 2009
Received: July 21, 2009

Dear Dr. Gowda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092197 pg 1 of 1

Indications for Use

510(k) Number (if known):

Device Name: PhoTex30 Diode Laser Series, Model 980nm, 810nm, 940nm

Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark P. Updegrove for mam

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092197